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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/646,110 | 11/05/2001 | Lillian E Dyck | 10242 34 | 3978 |
| 1059 | 7590 | 03/18/2004 | EXAMINER | |
| BERESKIN AND PARR SCOTIA PLAZA 40 KING STREET WEST-SUITE 4000 BOX 401 TORONTO, ON M5H 3Y2 CANADA | | | REYES, HECTOR M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1625 | |

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 09/646,110 | Applicant(s) DYCK ET AL. | |
| | Examiner Hector M Reyes | Art Unit 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06/27/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 24-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-16 and 24-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Lack Of Unity

Status of The Claims

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-10, 11-16, 25-31, in part, drawn to a series of:

- Compounds having formula I, wherein the variable x is a carboxyl group,
- Compositions embracing the said derivatives,
- Method of treatment or prevention the particular diseases described in claim 30

Classified in class 562, subclass 400+.

Group II, claims 1-10, 11-16, 25-31, in part, drawn to a series of:

- Compounds having formula I, wherein the variable x is a carbalkoxy group,
- Compositions embracing the said derivatives,
- Method of treatment or prevention the particular diseases described in claim 30

Classified in class 560, subclass 1+.

Group III, claims 1-10, 11-16, 25-31, in part, drawn to a series of:

- Compounds having formula I, wherein the variable x is cyano,
- Compositions embracing the said derivatives,
- Method of treatment or prevention the particular diseases described in claim 30

Classified in class 558, subclass 303+.

Group IV, claims 1-10, 11-16, 25-31, in part, drawn to a series of:

- Compounds having formula I, wherein the variable x is phosphonic acid,
- Compositions embracing the said derivatives,
- Method of treatment or prevention the particular diseases described in claim 30

Classified in class 562, subclass 8+.

Group V, claims 1-10, 11-16, 25-31, in part, drawn to a series of:

- Compounds having formula I, wherein the variable x is a phosphonate ester,
- Compositions embracing the said derivatives,
- Method of treatment or prevention the particular diseases described in claim 30

Classified in class 558, subclass 70+.

Group VI, claims 1-10, 11-16, 25-31, in part, drawn to a series of:

- Compounds having formula I, wherein the variable x is 5-tetrazole,
- Compositions embracing the said derivatives,
- Method of treatment or prevention the particular diseases described in claim 30

Classified in class 548, subclass 70+.

Group VII, claims 25-29 and 31, drawn to a series of methods for the treatment or prevention of any disease in which cell death occurs by apoptosis, as described in the said claims, classified in class 514, multiple s subclasses. Subject to further restriction. Election of a single disclosed specie required.

Group VIII, claim 24, drawn to a commercial package for the treatment or prevention of a disease in which cell death occurs by apoptosis, as described in the said claim, classified in class 206, subclass 828+.

The inventions listed as Groups I through VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Inventions outlined above are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions 1-VIII are different because they are not disclosed as capable of using together. For instance, the claimed method of use and pharmaceutical compositions are not required to use all the compounds from each one of the above groups. On the other hand, compounds embrace in one Group are not required to be used in the method of use or pharmaceutical compositions of compounds of another group. Similarly, a commercial package is not required to treat a any of

the diseases embraced in the other groups, while the diseases included in claim 30 are not the only diseases embraced by groups I through VI.

Indeed a given reference disclosing or suggesting any of the above groups under the meaning of 35 USC 102 or 35 USC 103 cannot be use to reject any of the other groups base upon the said articles.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for any of the above groups is not required for the other Groups, restriction for examination purposes as indicated is proper.

This application contains claims directed to more than one species of the generic invention.

These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

In group I, in claim 1 in part, carboxylic acid having different chemical structures

In group II, in claim 1 in part, carbalkoxy acid derivatives having different chemical structures

In group III, in claim 1 in part, cyano derivatives having different chemical structures

In group IV, in claim 1 in part, phosphonic acid derivatives having different chemical structures

In group V, in claim 1 in part, phosphonate esters derivatives having different chemical structures

In group VI, in claim 1, in part, 5-tetrazole derivatives having different chemical structures and

In group VII, in claim 25 in part, any disease in which cell death occurs by apoptosis.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each one of the derivatives although having the common general formula I also contain significant different functional groups thus they have a significant different chemical structure due to the variability of all variable moieties. Similarly, different diseases embraced in claim 25 can have different symptoms and alternative methods of treatments that may not treat other diseases, which are embraced in the said claim.

CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hector M Reyes whose telephone number is (571) 272-0691. The examiner can normally be reached on Monday to Friday from 9 am to 12m and 1 to 4pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms.

Rita Desai can be reached on (571) 272-0684.

Hector M. Reyes, Ph D JD

Reg. # P-54846

March 17, 2004

AU 1625

A handwritten signature in cursive script, appearing to read "RDesai", with a horizontal line drawn underneath it.

RITA DESAI
PRIMARY EXAMINER